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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,588	05/03/2001	Stephen Friend	215538.00108	7335

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EXAMINER	
LEFFERS JR, GERALD G	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,588	FRIEND ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-20 and 23-25) in Paper No. 7, filed 9/13/02, is acknowledged. However, upon further review of the pending claims, it has become evident that further restriction is required. In the restriction outlined below, each of the groups from the previous restriction has been further restricted based upon the primary gene defect or secondary lethal gene or gene product upon which the claimed invention is dependent.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-52. Claims 1-20, 23-25 drawn to methods of identifying secondary drug targets and using the identified secondary drug targets to screen candidate drug compounds, classified in class 435, subclass 6. Each of Groups 1-52 is directed towards a different and distinct gene comprising a primary genetic defect.

Groups 53-101. Claims 21-22, 30-46, drawn to pharmaceutical compositions and methods of treating cancer wherein the active ingredient interferes with the expression or activity of a secondary drug target, classified in class 514, subclasses 2, 44. Each of Groups 53-101 is directed to a different and distinct secondary lethal gene target.

Groups 102-144. Claims 26-29, drawn to pharmaceutical compositions comprising a mutated form of a secondary drug target, classified in class 514, subclass 2. Each of Groups 102-144 is directed towards a different and distinct secondary target gene or gene product.

The inventions are distinct, each from the other because of the following reasons:

Inventions within Groups 1-52 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and each of the groups is directed towards a primary genetic defect in a structurally and functionally distinct gene encoding a structurally and functionally distinct protein. Thus, the operation, function and/or effects of the different methods of the different groups are necessarily different and distinct from one another, and one does not render the others obvious.

Claim 1 link(s) inventions of Groups 1-52. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups 53-101 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions within Groups 53-101 are drawn to a different and distinct secondary lethal gene target and are not disclosed as usable together. Each of the specifically recited genes encodes a functionally and structurally distinct protein that has its own characteristics with regard to the agents with which it will interact. Therefore, the different methods of the different groups necessarily have different modes of operation, different functions and/or different effects, and one does not render the others obvious.

Claim 30 link(s) inventions of Groups 53-101. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions within Groups 102-144 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of the different groups are not disclosed as usable together and are directed towards a different mutated form of a secondary gene product, each of which has its own structural and functional characteristics. Thus, each of the different groups necessarily has different modes of operation, different functions and/or different effects. Therefore, one of Groups 102-144 does not render any of the other groups within Groups 102-144 obvious.

Claim 26 link(s) inventions within Groups 102-144. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 26. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups 1-52 and Groups 53-144 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and the operation, function and effects of the different groups are different. For example, the methods of Groups 1-52 are directed towards identifying a secondary lethal gene target (i.e. a gene whose mutation in the presence of a primary cell mutation results in a lethal effect for a given cell type) and using the identified secondary gene target to identify compounds that affect the expression or activity of the wildtype secondary gene target. This is biologically, functionally and operationally different from the methods/compositions of Groups 53-144, which are directed towards the effect of treating cancer in an individual. Thus, the operation, function and effects of the claims of Groups 53-144 differ from those of Groups 1-52.

Inventions of Group 53-101 and Groups 102-144 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together and have different modes of operation. The pharmaceutical compositions of Groups 53-101 comprise active agents that interfere with the expression of, or activity of, a wildtype secondary gene target. In contrast, the active ingredient of the pharmaceutical compositions of Groups 102-144 is the actual gene product of the mutated secondary gene target (or fragment of mimic thereof). Thus, the claims of the different groups are drawn to compositions that have very different means of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, the different groups require a different non-patent literature search (e.g. pharmaceutical compositions comprising an agent inhibiting expression of a target gene or the activity of the target polypeptide (Groups 53-101) and pharmaceutical compositions comprising a mutated form of a target polypeptide whose presence has a lethal effect on a cell having a primary defect (Groups 102-144). Within each of the larger groupings (i.e. Groups 1-52, 53-102 and 103-144) a different nonpatent literature search is required based upon the different and distinct gene or gene product upon which the claimed invention is based.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicants should clearly elect one of the specifically recited primary genes or secondary genes found within each of the groups.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggl
December 2, 2002